

Laboratory Technicians

The Clinical Laboratory Law and Its Meaning to Private Physicians

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THERE WAS A TIME when medical practice depended almost entirely on the power of observation and on the application of personal experience in the diagnosis and treatment of disease. Regardless of the diagnostic acumen of the physician, however, the diagnosis often was missed because of inadequate information. As time went on, many other factors were added to those fundamental facilities. The physician, instead of relying upon his own skills alone, drew assistance from the specialized abilities of others.

In the course of this development, the volume of knowledge relative to disease processes and how to measure them expanded beyond the belief of earlier generations. It became necessary to understand the processes of deranged anatomy and deranged physiology, and also the life cycles and metabolic processes of parasitic agents. The methods for determining these derangements require complex procedures through use of precise methods.

In this way the private physician came to need more than his own personal skill. He needed data from scientific measurements done by others than himself. He became the coordinator of a vast amount of scientific information in relation to his patients. As a corollary to this, he had to be assured that those who made the determinations were competent and that they used reliable instruments and methods.

Assistance to him in this assurance constitutes one of the functions of public health practice. As laboratory science has become more complex, the medical profession has, from time to time, recommended regulations designed to insure accuracy. These have received legal status through legislative action. The administration of these regulations has been carried on as part of the program of public health departments.

In California, the Clinical Laboratory Law as it exists today is the outcome of over a quarter century of cooperative development among components of medicine, including public health, and the legislature. As long ago as 1923, the State Board of Health authorized the director of the State Hygienic Laboratory to inaugurate a system of inspection and certification of diagnostic laboratories, both public

• *The present laws and regulations relating to clinical laboratories in California are the outcome of over a quarter century of cooperative development.*

The medical profession, public health department, laboratory workers, and the legislature have worked together in this development.

At first the system of certifying technicians and laboratories was on a voluntary basis. The clinical laboratory law in effect legalized and made generally applicable a system which had already been accepted voluntarily.

The application of the clinical laboratory law provides physicians a reasonable assurance that competence and reliability will prevail in clinical laboratory operation.

Of great importance is the conduct of proper training programs by approved laboratories.

Since modern medical practice is so dependent on accurate clinical laboratory work it is essential that special effort be directed by physicians toward influencing young people to enter the profession of medical technology.

and private.³ At first the system of examining and certifying clinical and public health technicians was conducted on an entirely voluntary basis. This system of voluntary acceptance of approval extended also to laboratories. By the time the first law was proposed, this voluntary system had become generally accepted by laboratory directors and technicians throughout the state. The law, in effect, legalized and made generally applicable a system of examination and certification which had already been operating on a voluntary basis for 15 years. The Clinical Laboratory Law which was made effective in 1938 was a cooperative venture in which all interested organizations participated. The law was revised in 1951 in keeping with advancements of knowledge and experience in clinical laboratory operation.

Since 1941, there have been two committees serving in an advisory manner to the State Department of Public Health in the administration of the law. These committees are composed of five members, each with representatives from the universities, pathologists, technologists and technicians.⁷

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TABLE 1.—*Chronology of activities in licensing of clinical laboratories and clinical laboratory personnel*

Date	Clinical Laboratory	Clinical Laboratory Personnel
Before 1925	No supervision	No supervision
1925-1937	Voluntary approval of clinical laboratories	Voluntary certificates in individual subjects for technicians
1937—Clinical laboratory law passed		Licenses for technicians and technologists required
1938—State Board of Public Health regulations adopted		Licensing initiated with blanketing in of laboratory workers
1941	Voluntary approval of clinical laboratories abandoned	
1942		Discontinued issuance of certificates in individual subjects
1947—State Board of Public Health regulations amended		Licensing in individual subjects; requiring graduate degree; reestablished
Laws and regulations amended 1951, effective January, 1952	Laboratory permits required	Registration of clinical laboratory trainees required

TABLE 2.—*California licenses issued for clinical laboratory technicians and technologists by year, 1938-1953*

Year	Technician	Technologist
1938.....	2	178
1939.....	326	32
1940.....	76	10
1941.....	228	62
1942.....	212	7
1943.....	182	4
1944.....	154	11
1945.....	183	8
1946.....	365	12
1947.....	547	26
1948.....	335	14
1949.....	178	3
1950.....	393	7
1951.....	418	9
1952.....	657	9
1953.....	526	13
Total.....	4,782	405

The law, as at present constituted, defines a clinical laboratory as follows: "Clinical laboratory means any place, establishment, or institution organized and operated for the practical application of one or more of the fundamental sciences by the use of specialized apparatus, equipment, and methods for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of disease in human beings."⁴

There are certain exemptions provided in this law, one of which recognizes the relationship between a physician and his patients in his private practice. Thus, the law does not apply to a clinical laboratory operated by "an individual licentiate of the healing arts for laboratory work performed on his own patients and within the scope of his license privileges." This does not permit, however, the laboratory to receive direct or indirect referred work from any other source. Other exemptions include laboratories operated by the state or federal government. Those permitted to perform tests in clinical laboratories are physicians, technologists, technicians, and trainees. Only a physician or a technologist may direct a laboratory.

Any of the above groups may do all procedures involved in laboratory operation. This includes skin puncture, or venipuncture for collection of specimens, and the performance of tests. It does not, however, include spinal puncture, except, of course, by a physician.² The activity of trainees is modified by the provision that their work be done under direct supervision of a licensed person, and there may be no more than one trainee per licensed person, and no more than two in any laboratory except where a training school has been approved.

Laboratories are operated under permits issued by the State Board of Health on recommendation by the Department of Public Health, after inspection of their operation and equipment. Licenses and permits are renewed annually.

Table 1 lists chronologically the various phases in the development of the present clinical laboratory act.

Since clinical laboratory practice demands accuracy and precision of its operators, it is important to know what kind of persons are doing the work, and something about their training and their numbers.

Table 2 lists the number of licenses issued to technicians and technologists each year since 1937.⁸ In general, the number of technician licenses issued has steadily increased each year since the post-war years of 1946 and 1947. There is noted a sharp peak in numbers immediately following the war which indicates the return of service men to civilian life.

The terms technician and technologist should be defined at this point, since not everyone is familiar with the nomenclature as it is applied in California.

The California Business and Professions' Code describes a clinical laboratory technician in Sections 1261 and 1262.⁴ For the sake of brevity, only certain items in that description will be dealt with here.

In general, it may be said that five years are required after high school graduation before an individual is qualified to take the examination for licensure.

These five years may be spent in several ways. The recommended procedure involves four years of college with a degree of bachelor of arts or bachelor of science and a major in bacteriology, biochemistry, medical laboratory technique or essentially equivalent subjects. This academic experience is then followed by actual clinical laboratory work in an approved laboratory as a trainee for a period of up to one year.

The length of time in traineeship depends on the content of the curriculum of the college from which the degree was received.

If the person completes only three years of college, including certain required subjects, then two years of traineeship is required.

If only two years of college is completed, with the required subjects, then three years of traineeship must be fulfilled. It is now possible to receive this minimum two years of required college instruction in most of the 75 junior colleges of the state.

In the past, high school graduates with five years of approved traineeship were qualified to take the examination. However, the present law has raised educational standards to a minimum of two years of college. This will be mandatory on and after January 1, 1957.

Now to consider the definition of clinical laboratory technologist. It must be remembered that this definition is based on the California statute (Sec. 1260).⁴ Again, reference will be made only to the high points in this legal definition.

Nine years following high school graduation is the minimum time requirement to qualify for the technologist examination. These nine years must include four years of resident instruction leading to a degree in an approved college or university. The courses shall contain certain minimum numbers of hours in pertinent subjects. There must also be five years of practical experience in an approved clinical laboratory, at least one year of which shall immediately precede admission to the examination. This examination includes written, practical and oral portions.

There are two exceptions which may be invoked in the application of the five years of experience. A master's degree in fundamental medical sciences may be substituted for one year of experience. A doctor of philosophy degree, on the same basis, may be substituted for two additional years.

It will be noted that technologists have considerable preparation before admission to the examination. This is considered essential, since technologists are the only persons, aside from physicians, who may operate and direct clinical laboratories. It has been recognized that laboratory direction by physicians, preferably specialists in pathology, is the desirable situation. However, this is impossible

TABLE 3.—Clinical laboratory technician and technologist licenses (California) by sex

License	— Issued 1938-1953 —			— Active in 1953 —		
	Total	Per Cent Male	Per Cent Female	Total	Per Cent Male	Per Cent Female
Technician	4,782	27.6	72.4	4,003	28.1	71.9
Technologist	405	46.4	53.6	339	45.4	54.6

TABLE 4.—Certificates of proficiency granted and limited licenses issued at time law became effective (California)

License or Certificate	— Issued —			— Active in 1953 —		
	Total	Per Cent Male	Per Cent Female	Total	Per Cent Male	Per Cent Female
Limited licenses..	395	19.7	80.3	157	19.1	80.9
Certificates of proficiency	2,451	20.9	79.1	109	16.5	83.5

Note: Certificates of proficiency granted 1928-1942.

at present, for there are not enough pathologists or other physicians interested in laboratory medicine to cover the various communities needing clinical laboratory service. The technologist, therefore, fulfills an important function in assisting practicing physicians in this essential field of medicine.

Sixty-seven and one-tenth per cent of all persons now licensed as technicians are college graduates, and 89.5 per cent have had at least some college education.

The amount of formal education is related to the ability to pass this examination: 91.3 per cent of those with college degrees pass; of those with some college training, but without a degree, only 72.9 per cent pass; of those with only high school training, 53.3 per cent pass.

Of the 4,255 persons who have taken the technician's examination during the past eight years, 2,481 or 58.3 per cent had college degrees.

Most clinical laboratory technicians are women, but the proportion has decreased slightly in recent years. Table 3 shows the relative numbers of men and women holding licenses as technicians and technologists. Seventy-two and four-tenths per cent of the technicians but only 53.6 per cent of the technologists are women.

Before the passage of the law in 1938, and for a limited period afterward, certificates of proficiency were issued in individual subjects. At the time the law went into effect, certain candidates were issued licenses in limited fields as part of the blanketing-in procedure. Data concerning these certificates and limited licenses are shown in Table 4. It will be noted that a majority of these certificates and licenses are no longer active, principally due to the fact that the persons to whom they were issued have obtained full licensure.

Besides clinical laboratory technicians and technologists, there remains another very important group to describe—clinical laboratory technician trainees. It is upon this group that the laboratory depends for continuity of operation and for expan-

TABLE 5.—Laboratories with permits, laboratories approved for training, and approved laboratory training schools, with number of trainees in each category (California, 1953)

	Total	—Type of Laboratory—			
		Hospital	Pet.	Other	Pet.
Laboratories with permits.....	843	315	37.4	528	62.6
Laboratories approved for training:					
Total laboratories approved....	346	167	48.3	179	51.7
Total trainees as of Dec. 1953..	392	263	67.1	129	32.9
Clinical laboratory—limit 2 trainees:					
Laboratories approved.....	321	144	44.9	177	55.1
Trainees as of Dec. 1953.....	260	144	55.4	116	44.6
Laboratory training school—one or more trainees:					
Laboratories approved.....	25	23	92.0	2	8.0
Trainees as of Dec. 1953.....	132	119	90.2	13	9.8

sion. It is for this class of worker that laboratory directors must take the initiative in providing training facilities. Time required in training varies as already described, depending on prior scholastic achievement.

Trainees are expected to work as technicians in every way, except that they are continuously under supervision, and are never on duty alone. Furthermore, no one may make a career of being a trainee; two years is the maximum time allowable, after meeting minimum qualifications, before a license must be obtained. It should be pointed out that trainees are paid for their work, usually an increasing amount, as they advance in experience.

Regulations contained in the California Administrative Code are precise in their description of the kind of training and experience to be provided for technician trainees.⁴

Laboratory directors may not accept trainees until the laboratories have been evaluated and approved for training by the State Department of Public Health. This evaluation includes equipment, personnel of the laboratories and scope of activities.

There are two kinds of training programs recognized. One is designed for the smaller laboratories, and under it not more than two trainees may be included, and not more than one if there is only one licensed person in the laboratory. The other kind of training program is for laboratories classified as training schools. In these schools, as many trainees may be registered as there are licensed personnel on duty. The schools must follow minimum schedules of experience and instruction and must have adequate equipment and volume and diversity of work.

Because the matter of training is of such great importance to the future supply of technical workers, the status of these programs will be discussed more extensively here.

TABLE 6.—Colleges and universities with curricula directed toward medical technology (California, 1953)

College or University	Number Enrolled	Enrollment Capacity (Estimated)
State universities (U.C., U.C.L.A., Med. School, San Francisco).....	239	370
State Colleges (7).....	253	350
Private colleges and universities (6)....	136	237
Total	628	957

Only 346 of the 843 approved clinical laboratories are conducting training programs (Table 5), and even they are not operating to the full capacity of their training potential. Therefore, in terms of numbers of laboratories participating in training, only about 41 per cent of the training potential is being used. Furthermore, in the 346 laboratories approved for training at the end of 1953, there were only 392 trainees listed in reports to the department. Since, in general, each laboratory may be approved for two trainees, the training in even these laboratories falls short of full capacity.

The principal source of trainees is the colleges and universities of the state. Table 6 shows the kinds of schools and colleges within the state that maintain curricula for medical technology. Also shown is the approximate enrollment in these colleges as compared with their capacity. While enrollment capacity is estimated at 957, only 628 students are actually enrolled. Thus, it is seen that both the educational institutions and the clinical laboratories are operating considerably below their capacity for training future technicians and technologists.

After this consideration of educational and training programs, the question follows as to whether or not these programs are producing sufficient personnel to meet the needs of our clinical laboratories.

Only 779 out of 4,782 persons have failed to maintain their licenses in an active state during the past 16 years. This represents a total loss of about 16 per cent. However, not all the licensed individuals are active as technicians. Many of them, for various reasons, are not actually engaged in laboratory work; but they represent a potential which is available in case of necessity.

It has already been noted that approximately 500 new licenses have been issued each year in recent years. Yet the technician shortage still appears to be acute. It thus seems evident that at least 500 to 600 new licentiates must be added each year to fulfill California's needs. To accomplish this, more students will have to be enrolled in courses of medical technology in educational institutions, and more facilities for trainees will have to be activated in the clinical laboratories.

Because of the difficulty in maintaining an adequate supply of qualified technicians, proposals are

occasionally received for establishing classes of technicians at lower levels of training. It is stated that these workers with less training could perform so-called simple laboratory procedures such as urinalysis and the common blood determinations. In consideration of these proposals, it should be stated that no laboratory procedures are looked upon as "simple." There is too much involved to allow performance of these tests to deteriorate to the mere pouring together of specimens and reagents, and empirically noting results.

In this connection, it has been noted that a few private schools have set up curricula designed to prepare individuals, often with limited background, for jobs as office assistants to professional people. These courses include some bookkeeping instruction, some simple nursing procedures, public relations principles, as well as a few of the more common laboratory tests. The state Attorney General has ruled that insofar as the teaching of laboratory technique is concerned, these schools are operating illegally.² Only where the laboratory technology training is given to prepare students for ultimate licensure is that training within the law. This ruling is further evidence of the importance of adequate training and experience in preparation for a career in medical technology.

What might be termed "a scientific conscience" is essential to successful performance in the laboratory, and this can only be developed through high level teaching and experience. The technician must have a deep appreciation of the importance of accuracy, and of the importance of the tests to the physician, as well as a pride in his role as a professional member of the medical team.

It has been stated already that individual physicians in their practice are exempt from the provisions of the clinical laboratory law so long as their laboratories perform tests for their own patients only. In spite of this exemption, there is an increasing use by private physicians of licensed technicians. As more such technicians become available, this practice will no doubt become more general. Unless a physician has the time to perform his own laboratory tests, good practice dictates that he have a licensed technician for this work.

As a corollary to this, it should be stated that private physicians may undertake premarital⁵ and prenatal⁶ serologic tests in their own offices on their own patients only when their laboratories are approved for this purpose by the State Department of Public Health, and this approval stipulates that all technicians performing such tests must be licensed.¹

It is clearly established that modern physicians are dependent on clinical laboratory techniques for accurate diagnosis and for maintaining successful treatment. Therefore, success in medical practice

demands that clinical laboratory work be done by well qualified technicians.⁹

To fill the need for qualified persons, it is necessary that many more of the young people of today be guided toward the profession of medical technology. Competition from other sources is keen. The training period is long, and the remuneration of these workers is small in the early stages of their careers. These factors are definitely a handicap to recruitment. Thus, it becomes a major responsibility of all private physicians to make the period of traineeship after academic training as attractive as possible. Salaries must be on a competitive level with other fields. Personal interest by private physicians will develop in technicians and trainees pride in their work, and personal satisfaction in being related to medical practice.

Unless aggressive promotion in this field is exerted by private physicians, it will be increasingly difficult to provide medical practitioners with the assistance available through scientific laboratory methods.

Some physicians are already taking time off from their practices to give lectures and instruction to students in state colleges. It is this sort of individual effort which stimulates young people to continue their studies in this field, and also to draw new recruits into the profession. Other physicians in the course of their daily rounds may drop in to the laboratory and indulge in spirited discussions with the technicians and trainees. It is through this kind of relationship that physicians may hope to compete with other private industry in influencing competent young people to enter the field of medical technology.

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